CLAIMS

What is claimed is:

1. A method of treating or preventing type 1 diabetes in a subject in need thereof, comprising: administering to the subject a pharmaceutically-effective amount of a composition comprising an immunoglobulin, or a portion thereof, linked to a peptide, wherein the immunoglobulin or portion thereof is aggregated.

2. The method of claim 1, wherein the subject is in a preinsultis stage of type 1 diabetes.

3. The method of claim 1, wherein the subject has not yet undergone IAA seroconversion.

4. The method of claim 1, wherein the subject is a human.

5. The method of claim 1, wherein the aggregated immunoglobulin, or portion thereof, can bind to an Fc receptor.

6. The method of claim 5, wherein the peptide is presented to T cells in association with MHC class II molecules.

7. The method of claim 6, wherein the composition is endocytosed by cells having an Fc receptor and is processed and presented by the cells in association with MHC class II molecules thereby preventing activation of diabetogenic T cells.

8. The method of claim 1, wherein the peptide is an INSß peptide.

9. The method of claim 8, wherein the administration of the composition delays the onset of type 1 diabetes.

10. The method of claim 1, wherein the composition induces production of IL-10.

11. The method of claim 1, wherein the immunoglobulin comprises Ig-INS and Ig-GAD.

12. The method of claim 1, wherein the immunoglobulin comprises Ig-INSß, Ig-GAD1, Ig-GAD2, or an immunoglobulin, or a portion thereof, linked to a peptide derived from GAD65 or an insulin protein.

13. The method of claim 1, wherein the immunoglobulin, or portion thereof, comprises human IgG, or is derived from human IgG or humanized IgG.

14. A method of treating or preventing type 1 diabetes in a subject expressing a type 1 diabetes predisposition marker, comprising: administering to the subject a pharmaceutically-effective amount of a composition comprising an immunoglobulin, or portion thereof, linked to a diabetogenic peptide.

15. The method of claim 14, wherein the subject is in an insulitis stage of type 1 diabetes.

16. The method of claim 15, wherein the subject has not yet developed hyperglycemia.

17. The method of claim 14, wherein the subject has seroconverted and produces auto-antibodies against one or more ß-cell-associated antigens.

18. The method of claim 17, wherein the subject is IAA-positive.

19. The method of claim 14, wherein the subject is a human.

20. The method of claim 14, wherein the immunoglobulin comprises soluble Ig-INSß.

21. The method of claim 14, wherein the immunoglobulin comprises Ig-INSß, Ig-GAD1, Ig-GAD2, or an immunoglobulin, or a portion thereof, linked to a peptide derived from GAD65 or an insulin protein.

22. The method of claim 14, wherein the immunoglobulin, or portion thereof, comprises human IgG, or is derived from human IgG or humanized IgG.

23. The method of claim 14, wherein the composition is endocytosed by cells comprising an Fc receptor, and is processed and presented by the cells in association with MHC class II molecules, thereby preventing activation of diabetogenic T cells.

24. The method of claim 14, wherein the composition is soluble.

25. A pharmaceutical composition, comprising: a pharmaceutically-effective amount of an immunoglobulin, or portion thereof, linked to a protein fragment or peptide, wherein the immunoglobulin, or portion thereof, can bind to an Fc receptor; the peptide comprising INSß, GAD 1, or GAD2.

26. The composition of claim 25, wherein the composition further comprises the property of being endocytosed by cells comprising the Fc receptor and processed by the cells to present the peptide to endogenous MHC Class II molecules, thereby preventing activation of diabetogenic T cells specific for the peptide.

27. The composition of claim 25, wherein the immunoglobulin comprises agg Ig-INSß, or sol Ig-INSß.

28. The composition of claim 25, wherein the peptide is inserted within a variable region of the immunoglobulin, or portion thereof.

29. The composition of claim 25, wherein the immunoglobulin comprises Ig-INS and Ig-GAD.

30. The composition of claim 25, wherein the immunoglobulin comprises Ig-INSß, Ig-GAD1, Ig-GAD2, or an immunoglobulin, or a portion thereof, linked to a peptide derived from GAD65 or an insulin protein.

31. The composition of claim 25, wherein the immunoglobulin, or portion thereof, comprises human IgG, or is derived from human IgG or humanized IgG.

32. The composition of claim 25, wherein the composition further comprises a pharmaceutically acceptable carrier.

33. The composition of claim 25, wherein the composition is formulated for intravenous delivery.

34. Use of a composition wherein the composition comprises a pharmaceutically-effective amount of an immunoglobulin, or portion thereof, linked to one or more peptides; wherein the immunoglobulin, or portion thereof, can bind to an Fc receptor and be endocytosed by an antigen presenting cell, and the one or more peptides, or fragments thereof, provide one or more T cell receptor engaging determinants for presentation on the surface of the antigen presenting cell upon endocytic processing for the preparation of a pharmaceutical composition for alleviating symptoms associated with type 1 diabetes for a subject in need.

35. The use of claim 34, wherein the immunoglobulin comprises Ig-INS and Ig-GAD.

36. The use of claim 34, wherein the immunoglobulin comprises Ig-INSß, Ig-GAD1, Ig-GAD2, or an immunoglobulin, or a portion thereof, linked to a peptide derived from GAD65 or an insulin protein.

37. The use of claim 34, wherein the immunoglobulin, or portion thereof, comprises human IgG, or is derived from human IgG or humanized IgG.

38. The use of claim 34, wherein the immunoglobulin, or portion thereof, is aggregated.

39. The use of claim 34, wherein the composition is soluble.

40. A method for presenting a T cell receptor engaging determinant on the surface of a professional or nonprofessional antigen presenting cell, comprising:

a) providing a composition comprising an immunoglobulin, or portion thereof, linked to one or more peptides derived from the group consisting of insulin and GAD; wherein the immunoglobulin, or portion thereof, can bind to an Fc receptor and be endocytosed by an antigen presenting cell; and the one or more peptides, or fragments thereof, provide one or more T cell receptor engaging determinants for presentation on the surface of the antigen presenting cell upon endocytic processing;

b) contacting the composition with at least one Fc receptor present on a surface of a professional or nonprofessional antigen presenting cell; wherein the composition is internalized by the antigen presenting cell; and

c) endocytically processing the internalized composition to provide one or more T cell receptor engaging determinants; wherein the provided T cell receptor engaging determinants are presented on the surface of the antigen presenting cell.

41. The method of claim 40, wherein the provided T cell receptor engaging determinant is presented on the surface of the antigen presenting cells associated with at least on MHC complex.

42. The method of claim 40, wherein the immunoglobulin comprises Ig-INS and Ig-GAD.

43. The method of claim 40, wherein the immunoglobulin comprises Ig-INS8, Ig-GAD1, Ig-GAD2, or an immunoglobulin, or a portion thereof, linked to a peptide derived from GAD65 or an insulin protein.

44. The method of claim 40, wherein the immunoglobulin, or portion thereof, comprises human IgG, or is derived from human IgG or humanized IgG. A method of treating or preventing a condition or disorder where treatment with an anti-diabetic type 1 agent is indicated, the method comprises administering the composition according to claim 21 to a subject in need of such treatment.

45. A kit for the treating or preventing type 1 diabetes, the kit comprising a composition according to claim 25.

46. A method of use of a composition according to claim 25 in manufacture of a medicament for treatment or prevention of a type 1 diabetes disease, condition or disorder.